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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,937	06/02/2000	Jeffrey A. Hubbell	50154/003001	6551

21559 7590 04/30/2004

CLARK & ELBING LLP
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BOSTON, MA 02110

EXAMINER

RILEY, JEZIA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/586,937

Applicant(s)

HUBBELL ET AL.

Examiner

Jezia Riley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-12, 17-21, 33 and 34 is/are allowed.
- 6) ☒ Claim(s) 13-16, 22-32 and 35-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s):

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/18/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 1/28/2004 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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3. Claims 13-16, 22-32, 35-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbell et al. (US5,573,934).

Hubbell discloses methods for coating and/or encapsulating surfaces and three-dimensional objects with cross-linked networks of water-soluble polymers.

Hubbell et al. discloses, biocompatible polymeric materials which are formed for use in juxtaposition with biologically active materials or cells and tissue, by free radical polymerization of biocompatible water soluble macromers including at least two polymerizable substituents. These polymeric coating materials can be either homopolymers, copolymers or block copolymers. As used herein, a polymer is a unit formed having a degree of polymerization greater than 10, and an oligomer has a degree of polymerization of between 2 and 10, degree of polymerization meaning the number of repeat units in the structure, e.g., d.p.=3 refers to a trimer. Polymerization of a component that has at least two polymerizable substituents is equal to gelation; the polymerization proceeds to form a three-dimensional, cross-linked gel. (co. 5).

The water soluble macromers can be polymerized around biologically active molecules to form a delivery system for the molecules or polymerized around cells, tissues, sub-cellular organelles or other sub-cellular components to encapsulate the biological material. The water soluble macromers can also be polymerized to incorporate biologically active molecules to impart additional properties to the polymer, such as resistance to bacterial growth or decrease in inflammatory response, as well as to encapsulate tissues. A wide variety of biologically active material can be

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encapsulated or incorporated, including proteins, peptides, polysaccharides, organic or inorganic drugs, nucleic acids, sugars, cells, and tissues (col. 8).

A variety of methods can be employed to form biocompatible overcoats, depending on the physical and chemical nature of the surface. Hydrophilic surfaces can be coated by applying a thin layer (for example, between 50 and 300 microns in thickness) of a polymerizable solution such as PEG diacrylate containing appropriate amounts of dye and amine. (col. 14).

Therefore the reference disclose making a biomaterial composition comprising attaching a pharmaceutical material to a molecule comprising a nucleophilic moiety. One of ordinary skill in art would be able to modified said procedure in order to achieve the instant invention using simple organic chemistry knowledge such as removing protective group which is well known in the art.. Further In summary, there is a need for materials, and methods of use thereof, which can be used to encapsulate cells and tissues or biologically active molecules which are biocompatible, do not elicit specific or non-specific immune responses, and which can be polymerized in contact with living cells or tissue without injuring or killing the cells, within a very short time frame, and in a very thin layer. An important aspect of the use of these materials in vivo is that they must be polymerizable within the time of a short surgical procedure or before the material to be encapsulated disperses, is damaged or dies. (Hubbell col. 3).

4. Claims 5-12, 17-21, 33, 34, are allowed.

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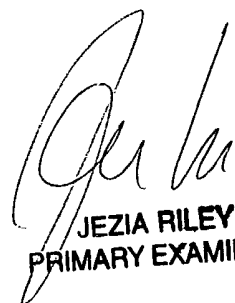
5. The references were lined in the PTO 1449, because they have not been provided by applicants or were not in the file.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thursday, April 29, 2004



JEZIA RILEY
PRIMARY EXAMINER